

**Amendments to the Specification:**

Please replace the Title of the Invention with the following amended Title of the Invention:

~~Process For~~ Method of Treatment Directed to Agent Retention In Biological Tissues

Please replace the paragraph that begins on page 13, line 19, and also begins with the following phrase, “The attachment of the barrier is independent of the internal structure of the tissue walls, . . . ,” with the following amended paragraph:

The attachment of the barrier is independent of the internal structure of the tissue walls, so the barrier may be effective for use with any variation of vessel. The general structure of the vessel depicted in Figure 1 may be representative of any artery or vein, since either vessel has similar layers in its wall. Some variations among vessels include ~~more~~ more elastic tissue in the tunica media of large arteries ~~and more~~ and more smooth muscles in this inner layer in small arteries. Also, the tunica media of veins is typically lean in smooth muscle and elastic tissue. Many large veins have a thick tunica adventitia including elastic tissue and smooth muscle along with collagenous fibers.

Please replace the paragraph that begins immediately below the heading “Agent” on page 19, line 24, and also begins with the following phrase, “In general ‘pre-treatment’ agent refers to agent contacted with the target site, . . . ,” with the following amended paragraph:

In general “pre-treatment” agent refers to agent contacted with the target site, *e.g.* tissue, before the barrier contacts the tissue. Similarly, “post-treatment” agent refers to agent that is

contacted with the target site, *e.g.* tissue, after the barrier contacts the tissue. The retention system may be used to prolong the residence time of any convenient agent that assists in diagnosis, research, therapy and disease prevention. The agent may be naturally and synthetically occurring substances, drugs, growth factors, gene therapy compositions, chemotherapeutic chemicals, anti-bacterial chemicals, ions, cells, small and large molecules, other agents, and any combination thereof. The term, "drug" is a chemical capable of administration to an organism which alters the organism's physiology. Drugs include well recognized pharmaceutical, such as those listed in "Drug Facts and Comparisons", 4<sup>th</sup> ed. 2000; "The Physicians Desk Reference," 49<sup>th</sup> ed., 1999; ; "Goodman and Gilman's The Pharmacological Basis of Therapeutics" 9<sup>th</sup> ed. (1995), pgs. 103-1673; and "The United States Pharmacopeia, The National Formulary," USP 23 NF 18 (1995) USP 23 NF 18 (1995). Drugs also include compounds that have indicated properties that are not yet formally recognized. Usually the agent is therapeutic in nature. The agents may be useful in pre-treatment and/or post-treatment of tissue with the barrier, where the pre- and post-treatment agent may be the same or different chemicals and concentrations.

Please replace the paragraph that begins on page 20, line 10, and also begins with the following phrase, "In particular uses, the agent may be an anti-proliferative drug for inhibiting cell proliferation, . . . ," with the following amended paragraph:

In particular uses, the agent may be an anti-proliferative drug for inhibiting cell proliferation, *e.g.* antibiotics, anti-metabolites, cytotoxic agents, steroids, hormones, anti-parasitic, anti-platelet, anticoagulants, calcium channel blockers, anti-hyperlipemics, receptor blockers, anti-connective tissue agents, anti-smooth muscle agents, and endothelial growth stimulators. More specifically the anti-proliferative agent may be ~~Taxol~~<sup>®</sup> TAXOL<sup>®</sup> from Bristol-Myers Squibb Co. located in NY; ~~Taxotere~~<sup>®</sup> TAXOTERE<sup>®</sup> from Rhone-Poulenc Rorer S.A. located in Antony, France; Heparin Sodium from Pharmacia & Upjohn Co. located in Michigan and COSMEGEN<sup>®</sup> Cosmogen from Merck & Co. located in NJ. Furthermore, the

agent may be anti-thrombotic, anti inflammatory, anti-fibrotic, anti-migratory and immune suppressive agents.

Please replace the paragraph immediately following the heading “Delivery Vehicle” that begins on page 20, line 27, and also begins with the following phrase, “The retention system according to the present invention includes a delivered vehicle . . . ,” with the following amended paragraph:

The retention system according to the present invention includes a ~~delivered~~ delivery vehicle for administering the barrier. The same or different vehicles may be used to dispense the agent and barrier. At times, the barrier is directly administered to the target site with a conduit and a post-treatment agent is administered by widespread perfusion of the area. For example, the body may receive a systemic, intravenous injection of the post-treatment agent. At other times, both the pre-treatment agent and barrier are directly applied, for example, with a conduit.

Please replace the paragraph that begins on page 21, line 15, and also begins with the following phrase, “Some exemplary techniques for applying the materials include invasive surgical procedures . . . ,” with the following amended paragraph:

Some exemplary techniques for applying the materials include invasive surgical procedures and minimally invasive surgical procedures, such as laparoscopic processes and percutaneous transluminal processes. Preferably the ~~deliver~~ delivery device for administering the barrier is the same device that is used to present the agent.

Please replace the paragraph that begins on page 23, line 3, and also begins with the following phrase, “Some exemplary post-treatment agents include antithrombotic drugs (such as heparin, prostacyclin, salicylates), . . . ,” with the following amended paragraph:

Some exemplary post-treatment agents include antithrombotic drugs (such as heparin, prostacyclin, salicylates), blood plasma proteins (such as albumin), thrombolytic agents (such as streptokinase, urokinase, TPA, APSAC), anti-inflammatory agents (such as steroidal and nonsteroidal drugs), combinations thereof, and ~~the like. In still the like. In still~~ another embodiment, as shown in Figure 2B, the tissue **70** with barrier **76** with binding member **78** on two opposing surfaces **72** and **74** is both pre-treated and post-treated with agents **80** and **82**, respectively. According to this retention process, agent **80** is administered, the barrier **76** is subsequently attached to two surfaces **72** and **74**, and then agent **82** is presented. The agents **80** and **82** may be the same type of agent or different types of agents. For example, agent **80** may be an anti-proliferative drug and agent **82** may be an anti-clotting drug, such as heparin.

Please replace the paragraph that begins on page 25, line 8, and also begins with the following phrase, “The amount of barrier to be administered into a patient will vary with the barrier, . . . ,” with the following amended paragraph:

The amount of barrier to be administered into a patient will vary with the barrier, the agent, delivery vehicle, treatment, etc. The barrier concentration should be related to the barrier binding member's relative affinity for the tissue surface and the concentration of agent used. As the affinity of the barrier for the tissue surface increases, the required concentration of the appropriate barrier will decrease. Optimization of the barrier to provide maximum agent retention should be ~~earlier~~ carried out using the methods described herein, once the barrier ~~have~~ has been decided upon.

Please replace the paragraph that begins on page 27, line 3, and also begins with the following phrase, “The material may be ejected into the interior of the vessel or organ . . . ,” with the following amended paragraph:

The material may be ejected into the interior of the vessel or organ from the surface or tip of the catheter. The material may be positioned on a balloon, such as a standard angioplasty balloon catheter, microporous balloon catheter, or infusion catheter. In addition, the ~~polymer~~ material may be administered by spraying, extruding or otherwise internally delivering the material by a tubular device having multiple lumens.

Please replace the paragraph that begins on page 28, line 22, and also begins with the following phrase, “A microporous balloon catheter is inserted through the rotating hemostatic valve (RHV) . . . ,” with the following amended paragraph:

A microporous balloon catheter is inserted through the rotating hemostatic valve (RHV) and secured. The agent used is 0.01 % w/v of Poly(amine) Barrier. The agent is delivered through the catheter at 3.5 atm pressure for 2 minutes in both control and test samples. The amount of agent delivered is about ~~3ml~~ 3 ml. Immediately following agent introduction, a barrier of Poly(amine) Barrier is delivered through the catheter in only the test samples for about 2 minutes. The total amount of barrier introduced is about 3 ml.

Please replace the paragraph that begins on page 29, line 10, and also begins with the following phrase, “Figures 4A to 4B show images of proximal, mid and distal sections . . . ,” with the following amended paragraph:

Figures 4A to 4B show images of proximal, mid and distal sections of the vessel wall exposed to agent. A sample fluorescent image of a control vessel treated with cascade blue alone is depicted in Figure 4A. The test vessel with cascade blue followed by poly-L-lysine, as illustrated in Figure 4B, has greater intensity, representing a larger amount of agent retained. Both Figure 4A and 4B show that the highest intensity is at the luminal intima and decreased intensity along the thickness of the vessel wall.